

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

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NEW YORK STATE RESTAURANT ASSOCIATION,

Plaintiff,

-against-

No. 2008 Civ. 1000 (RJH)

NEW YORK CITY BOARD OF HEALTH, NEW YORK  
CITY DEPARTMENT OF HEALTH AND MENTAL  
HYGIENE, and THOMAS R. FRIEDEN, In His Official  
Capacity as Commissioner of the New York City  
Department of Health and Mental Hygiene,

Defendants.

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**DECLARATIONS IN OPPOSITION TO PLAINTIFF'S MOTION FOR  
DECLARATORY AND PRELIMINARY INJUNCTIVE RELIEF**

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Of Counsel

February 8, 2008

KRUEGER  
DECL.

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

-----X  
NEW YORK STATE RESTAURANT  
ASSOCIATION,

No. 08 Civ. 1000(RJH)

Plaintiff,

-against-

NEW YORK CITY BOARD OF HEALTH,  
NEW YORK CITY DEPARTMENT OF HEALTH  
AND MENTAL HYGIENE, and Thomas R. Frieden,  
In His Official Capacity as Commissioner  
Of the New York City Department of Health  
And Mental Hygiene,

**DECLARATION OF  
BRUCE F. KRUEGER**

Defendants.  
-----X

BRUCE F. KRUEGER, hereby declares under penalty of perjury:

1. I am the Director of Graphics in the Bureau of Operations of the New York City Department of Health and Mental Hygiene (the "Department"). As part of my duties, I am required to create graphic materials, including, but not limited to, brochures, flyers, forms, posters, and review the work of other artists within and outside the Department, that are used in production of health education materials in the Department's Print Shop.

2. At the request of Mary T. Bassett, the Department's Deputy Commissioner for Health Promotion and Disease Prevention, in mid-March, 2007, I reviewed the proposal for calorie display submitted by Dunkin' Donuts.

3. Dunkin' Donuts had submitted a sample menu board in an attempt to demonstrate that calorie information would not fit along with price information unless the type size for both calories and prices would be so small as to be unreadable.

4. From that sample, I produced a replica of the menu board with comparable fonts and layout to demonstrate that calories could be listed easily and visibly (See Figure 1). I shortened the term "Calories," which headed the columns on the Dunkin' Donuts modification left room for displaying price and calorie information in their respective columns in larger, easily readable type. This illustration shows that the calorie listings required by the regulations are feasible to implement with basic graphic design techniques.

	Cal	Sm	Col	Med	Col	Lg	Col	X-lg
COFFEE	14	1.29	20	1.59	28	1.89	34	21.9
ICED	15	1.29	22	1.59	30	1.89		
Original • Decaf • Flavored								
TURBO HOT™	14	2.19	20	2.59	28	2.69	34	21.9
ICED	15	1.29	22	1.59	30	1.89		
Coffee with a shot of Espresso								
LATTE	116	2.19	136	2.59	232	2.69		
ICED	124	1.29	199	1.59	359	1.89		
Espresso & Milk								
Available in Caramel or Mocha Syrup								
LATTE LITE	14	2.19	20	2.59	28	2.69		
ICED	15	1.29	22	1.59	30	1.89		
ESPRESSO	4							
CAPPUCCINO	85	2.19	136	2.59	170	2.69		
BOX O' JOE™							140	9.99
COFFEE BY THE POUND								6.99

Figure 1. Menu board sample supplied by Dunkin' Donuts (left) vs. DOHMH adaptation of Dunkin' Donuts sample menu board (right).

I declare under penalty of perjury pursuant to 28 U.S.C. §1746 that the foregoing is true and correct.

Executed on February 6 2008.

  
BRUCE F. KRUEGER

**DUFFEY  
DECL.**

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

-----x  
NEW YORK STATE RESTAURANT  
ASSOCIATION,

Plaintiff,

2008 Civ 1000

-against-

NEW YORK CITY BOARD OF HEALTH,  
NEW YORK CITY DEPARTMENT OF HEALTH  
AND MENTAL HYGIENE, and Thomas R. Frieden,  
In His Official Capacity as Commissioner  
Of the New York City Department of Health  
And Mental Hygiene,

DECLARATION OF  
KIYAH J. DUFFEY

Defendants.  
-----x

KIYAH J. DUFFEY hereby declares under penalty of perjury:

1. Under the supervision of Dr. Barry M. Popkin and Dr. Penny Gordon-Larsen, I have conducted longitudinal, published research examining the associations between away-from-home food consumption and weight gain, diabetes, and components of the metabolic syndrome. In particular, my research has focused on differentiating the effects of long-term consumption of fast food from food consumed at more traditional, "family-style" sit down (or full service) restaurants. Additionally, I have examined long-term beverage consumption patterns and the associations between patterns of food and beverage consumption in an attempt to understand how the combination of food and beverage contributes to weight gain and incident obesity. To date, I have authored eight articles on these topics which have been published in peer reviewed journals or are currently in press, and presented work widely at national conferences for The Obesity Society and The American Society of Nutrition. In collaboration with Active Living Research, I served as planning co-chair for a workshop studying the environmental determinants of obesity. I am a member of the Obesity Society, American Society for Nutrition, Society for Epidemiologic Research, and the Population Association of America.

**Materials used, references made**

2. The following declaration is made in regards to NYC Board of Health's *Notice of Adoption of a Resolution To Repeal and Reenact §81.50 of the New York City Health Code* (hereafter R81.50). For this declaration, I also reviewed the Declaration of David Allison, PhD, including many of the original articles cited in this document. Additionally, I have conducted a review of the scientific literature and cite in the references to this document those papers which I believed to be most relevant to the topic. This Declaration is primarily in response to the Declaration made by Dr. Allison.

**Obesity is one of the fastest growing health problems in the US**

3. Obesity has risen dramatically in the past few decades among all race, gender, and age groups <sup>1-3</sup> and now affects nearly one-third of the American adult population <sup>3</sup>. Among adolescents (aged 12-19 years) there was a near tripling of the prevalence of overweight from 5% through the 1980s to 16% in 2002 <sup>4</sup>, which is of great concern due to observed tracking of weight and other anthropometric factors from young to later adulthood <sup>5-7</sup>.
4. Obesity is a complex disease associated with numerous adverse health outcomes <sup>8-10</sup> and is a risk factor for chronic conditions such as heart disease, stroke, cancer, diabetes, osteoarthritis, sleep apnea and psychosocial problems- to name a few. Excess death due to obesity was recently estimated at 112,000 people <sup>11</sup>- making obesity the second leading contributor to premature death.

**Adverse macronutrient profiles associated with fast food**

5. Fast food tends to be higher in total calories, total & saturated fat, and refined carbohydrates <sup>12, 13</sup>. Persons who regularly consume food away from home have diets characterized by greater energy density <sup>14</sup>, higher total energy intake per day <sup>14, 15</sup> and per eating occasion <sup>16</sup>, a higher percent of energy from fat <sup>17, 18</sup>, increased consumption of carbonated soft drinks <sup>19</sup>, and lower intakes of fiber <sup>16, 20</sup>, Vitamins A and C <sup>19</sup>, and fruit, vegetables and dairy products <sup>19, 21</sup>. Certainly there is a selection of healthier food options at many fast food places (e.g. salads at McDonalds) but the size and pricing tends to favor foods that are higher in energy, fat, and refined carbohydrates <sup>22</sup>.

6. Longitudinal studies, although small in number, and conducted primarily in adolescents, support the reported cross-sectional findings. Schmidt et al. followed a biracial cohort of females (aged 10 at baseline) for ten years and found that the frequency of fast food consumption increased as the girls aged, and that fast food intake was positively associated with total energy and saturated and total fat<sup>18</sup>. Similar results were observed among women, aged 20-45, who were followed for three years<sup>23</sup>. Without compensation through increased energy expenditure or reduced caloric intake at other eating occasions, such increases in dietary intake could lead to considerable weight gain, especially among young adults whose diet quality and diet preferences seem to track from young to middle adulthood<sup>24, 25</sup>.
7. Fast foods tend to be served in larger than average portion sizes<sup>26-29</sup> which has been shown to be associated with increased caloric intake at a single meal<sup>30</sup> and over several days<sup>31, 32</sup> with changes in portion size associated with changes in energy intake that are in the same direction (i.e. increased portion sizes lead to increased energy intake)<sup>33, 34</sup>.
8. Given the complex nature of the condition, few scientists believe that obesity is “caused” by any single factor, however most would support the statement that food packaging and marketing, including that of fast foods, are important contributors. A 2007 report published by the World Cancer Research Fund-American Institute for Cancer Research called fast food consumption a “probable cause of obesity” and cited several meta analyses that fast food restaurant use was convincingly linked with obesity<sup>35</sup>. To quote: “The evidence that ‘fast foods’ as defined in the literature are a cause of weight gain, overweight, and obesity is strong and consistent.... ‘fast foods’ are promoted vigorously, are cheap, and are often available in large portion sizes at low cost. ‘Fast foods’ probably cause weight gain, overweight, and obesity. They have this effect by promoting excess energy intake.” For these reasons, the panel’s Public Health Goals and Personal Recommendations state “consume fast foods sparingly, if at all”<sup>35</sup>.



**Association of away-from-home eating with obesity**

9. Increasingly, Americans are consuming foods obtained outside the home with just under 50% of food dollars spent on away-from-home foods<sup>36</sup>. Although rates have increased among all age-gender groups, the greatest change was observed among males aged 18-39, who consumed 39% of their daily calories away from home<sup>16</sup>.
10. The parallel trends of increased food away from home (in particular fast food) and obesity beginning in the 1980s provide ecological-level evidence of a link between the two. Frequent consumption of restaurant and fast foods has been cross-sectionally associated with higher BMI<sup>14, 37</sup> body fatness<sup>15</sup>, and prevalent overweight and obesity<sup>17, 19</sup>.
11. These associations are observed prospectively as well, which was not discussed in Dr. Allison's declaration. Among roughly 3,000 adults, Pereira et al.<sup>38</sup> found that change in weekly fast food frequency was positively associated with 15-year weight gain. Furthermore, greater change in fast food frequency was associated with greater change in insulin resistance (HOMA Scores) in both Blacks and Whites. Another prospective study found that women who reported an increase of 1 fast food meal per week over a 3-year period gained an additional 1.6 lbs over the average 3-year weight gain of 3.7 lbs<sup>23</sup>.
12. Finally, we have shown over 3 and 13-year periods that both baseline and change in fast food, but not restaurant food, consumption frequency is associated with greater changes in BMI and fasting glucose levels<sup>39, 40</sup> and that these effects may differ by baseline status (e.g. 13-year change in BMI is greater for those with higher baseline BMIs)<sup>40</sup>.

**Issues with studies used as evidence against a role for away-from-home consumption in obesity**

13. The following studies are used by Dr. Allison in support of a lack of evidence against a relationship between away-from-home food consumption and weight, weight change, or obesity. However, there are crucial limitations to these studies that should cause us to question the conclusions he draws.

- a. Sanigorski et al.<sup>41</sup> found no association between fast food intake and weight status among Australian children, however intake was reported by the child's parent or guardian, and a full 83% of the sample reported *zero* weekly intake of fast food. With just 2.3% of the sample reporting consumption of >1 time/week, statistical power to detect an effect is severely limited.
- b. Sturm & Datar<sup>42</sup> found that there was no significant effect of fast food price on 3-year BMI changes in a sample of kindergarten-aged children, once they had controlled for individual level factors. Food prices, however, were limited to the participant's city (rather than neighborhood) or the greater metropolitan area, which may not directly reflect food prices faced by an individual. Furthermore, they did not assess intake and thus the possible pathways from area-level food price to individual-level health outcomes cannot be assessed.
- c. French et al.<sup>17</sup> found that while frequency of fast food restaurant use [FFFRU] was positively associated with intake of total energy (in addition to other macronutrients and specific food groups) it was unrelated to BMI in females (7-12<sup>th</sup> grade) and slightly negatively associated with BMI in males. However, these findings should be interpreted with caution as the difference was not clinically significant (BMI 23.2 vs. 22.4) and greater FFFRU was also highly positively associated with participation in team sports among males. Finally, as these data are cross-sectional, confounding by unobserved variables (which could account for the observed relationships) is a possibility.

#### **Speculated harmful effects of menu labeling vs. demonstrated beneficial ones**

14. Dr. Allison uses several studies as support for the speculation that menu labeling might be harmful to consumers. Of course, it is possible that actions, any actions, have unintended and unforeseen consequences which may be detrimental to the public's health- and it is important to consider what these might be. However, some of the studies cited by Dr. Allison as evidence for menu labeling doing "more harm than good" deserve a closer look.

a. Creating distaste for healthier foods

**Dr. Allison States:** Using data from a CDC sponsored 2004-2005 study <sup>43</sup>, Dr. Allison states that “results showed a decreased preference for fruits and vegetables, belief that they [5<sup>th</sup> grade students] could eat more vegetables, and a willingness to try new fruit and vegetables...In other words, for these children, the seemingly innocuous intervention [distributing free fresh fruits and vegetables] seemed to make things worse.”

**Upon Closer Inspection:** Although over the course of one school year there was a slight, but significant, decline in the preference, belief and willingness of 5<sup>th</sup> grade students to try new fruits & vegetables (F&V), many positive changes were observed among the 8<sup>th</sup> and 10<sup>th</sup> grade students including increased preference (8<sup>th</sup> & 10<sup>th</sup> grade), increased positive attitudes towards F&V (8<sup>th</sup> grade), and an increase in actual consumption of fruits (8<sup>th</sup> & 10<sup>th</sup> grade) <sup>43</sup>. Furthermore, the 25 participating schools were competitively selected to participate, which is far from the RCT model that Dr. Allison calls for as sound scientific evidence.

b. Worsening the publics' diet

**Dr. Allison States:** Using data from a study by Aaron et al. <sup>44</sup> Dr. Allison states “EXP [experimental] subjects had significantly increased total energy, grams fat, grams carbohydrates and decreased grams protein and % energy from protein in week two vs. week one...Thus Aaron et al's results were opposite to the intention of providing nutrient and calorie information and *worsened* subjects' diets.”

**Upon Closer Inspection:** True, the authors of this study report that the experimental group (which was exposed to calorie labeling in on lunch entrees during the second of a two week study) had a statistically significant (albeit relatively small, 53 kcals) increase in total energy intake, Dr. Allison failed to point out that this increase was observed among the “low restraint” eaters only, thus conclusions about the effect of the experimental condition should not be extrapolated to the study group as a whole. Other important issues that limit the credibility of this study as support that menu labeling might be detrimental to New York City's public include:

- i. This study was conducted in a small group of subjects (n=90) that represent a specific population, which differs from the population that would be affected by R81.50.
- ii. Differences in intakes did not account for potential confounding factors that might also have affected food choice, such as price differentials between the lower calorie and high calorie options.
- iii. Most subjects stated that they had not been influenced by the menu labeling (which does not suggest a harmful effect as Dr. Allison suggest), however two thirds of the students felt they would occasionally use the labels if they were introduced again in the future.

c. Creating a desire for “forbidden” foods

**Dr. Allison States:** Dr. Allison uses a study by Jensen et al.<sup>45</sup> to suggest that by providing caloric information, R81.50 would generate greater interest in foods seen as ‘decadent’ or ‘forbidden’.

**Upon Closer Inspection:** I believe this statement is hyperbole. Labeling does not physically limit access to these higher calories foods (as is done in the cited paper<sup>45</sup>), but rather provides valuable information that patrons can use to make informed decisions about their food choices. Furthermore, this study found that there were no significant differences in the consumption amounts of this “forbidden” food (between those who were restricted and those who were not) and that children whose parents maintained a moderate level of restriction in the home actually consumed fewer kilocalories<sup>45</sup>.

15. Evidence also exists which suggests that menu labeling, such as that proposed in R81.50, would produce beneficial effects. Some examples are provided below.

- a. Mandatory nutrition labeling on packaged foods has led to the reformulation of numerous existing products, resulting in the introduction of new, nutritionally improved products, and increased consumer awareness about the effects of consuming certain dietary components<sup>46</sup>. For example, in the first four years after implementation, the number of available fat-modified cheese products tripled, and the market share for fat-modified cookies increased 15%<sup>47</sup>. Requirements for labeling of

*trans*-fats resulted in the adoption of healthier preparation techniques and ingredients used at many fast food chains<sup>48, 49</sup>, and labeling of menu boards would likely spur similar improvements in other aspects of menu offerings.

- b. A study conducted in 55 vending machines located in 12 secondary schools and 12 worksites found that signage highlighting healthier snack options was associated increases in low-fat snack sales<sup>50</sup> over the course of one year.
- c. A recent study of higher 41 senior menu development and marketing executives at leading casual dining and fast-food restaurant chains found that profit margins are the primary determinants of why food retail outlets do or do not add or continue to serve a given food item<sup>51</sup>. Without increased consumer demand, healthier food items are not likely to be offered in increased numbers. However, a recent study of consumer knowledge found that most consumers were unaware of the high levels of calories, fat, and sodium found in many menu items<sup>52</sup>. Without knowledge of what they are currently consuming, consumers cannot demand healthier options.

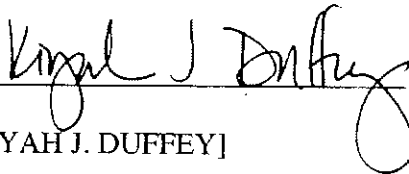
### **Summary**

16. In summary I believe that (1) regular and increased consumption of fast food has been associated with weight, weight gain and other obesity-related conditions (e.g. diabetes) in cross-sectional and prospective, longitudinal studies. These findings have been repeated in a variety of populations. (2) As stated earlier, obesity is a complex condition whose etiology is not completely understood. However, enough is known about many of the factors leading to obesity, that an absence of actions and policies addressing the problems should no longer be tolerated. (3) A majority of studies report some benefit to consumer dietary intake or affect on their purchasing decisions when caloric information is provided. Consumers also report that calorie labeling would be utilized but would be most effective at the point of purchase (such as menu boards) so that informed decisions can be made before purchases. (4) Although there are some limitations to the current body of evidence regarding the efficacy of calorie labeling at preventing weight gain, the most ideal type of study (i.e. a randomized

clinical trial) is not ethically plausible. On balance, I believe that the available evidence supports the use of calorie labeling (provision of calorie information) as one method to address and rising rates of obesity.

I declare under penalty of perjury pursuant to 28 U.S.C. §1746 that the foregoing is true and correct.

Executed on February 7, 2008

  
[KIYAH J. DUFFEY]

## References

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**ST-ONGE  
DECL.**

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK**

-----X  
**NEW YORK STATE RESTAURANT  
ASSOCIATION,**

**Plaintiff,**

**2008 Civ 1000**

**-against-**

**NEW YORK CITY BOARD OF HEALTH,  
NEW YORK CITY DEPARTMENT OF HEALTH  
AND MENTAL HYGIENE, and Thomas R. Frieden,  
In His Official Capacity as Commissioner  
Of the New York City Department of Health  
And Mental Hygiene,**

**DECLARATION OF  
Marie-Pierre St-Onge**

**Defendants.**  
-----X

I, Marie-Pierre St-Onge, Ph.D, hereby declares under penalty of perjury as follows:

1. I am Assistant Professor at the Institute of Human Nutrition, Columbia University and Research Associate at the New York Obesity Research Center, St. Luke's/Roosevelt Hospital. The New York Obesity Research Center is one of four federally funded Obesity Centers in the Country. In my current position and previous positions, I have studied the effects of various nutrients on energy balance and conducted several weight loss and controlled feeding studies in children and adults. I received a Ph.D in nutrition at McGill University, Montreal, Canada in 2003 and a completed post-doctoral fellowship at Columbia University in 2002-2004.
2. I am a Fellow member of NAASO: The Obesity Society and a member of the American Society of Nutrition and the American Heart Association. I have received several awards, namely the 2005 International Life Sciences Institute North America

Future Leader Award, the 2004 American Society for Clinical Nutrition Young Investigator Award and the 2003 American Heart Association New Investigator Award.

3. Over the past few decades, food and home environments have changed tremendously. In my own published review of current food patterns of children and associations with increasing weight,<sup>1</sup> environmental influences that affect eating behaviors include increased reliance on foods consumed away from home; food advertising, marketing, and promotion; and food prices<sup>2</sup>. Furthermore, there are more families in which both parents work, and time limitations have become an important factor in determining the types of foods consumed. The food industry responded to these new family issues by increasing the numbers of convenience foods and prepared meals available.<sup>3</sup> In addition, portion sizes have increased over the past two decades.<sup>4</sup>

4. Studies have shown that the proportion of foods eaten away from the home, particularly in fast food outlets and chains, has increased in the past decades and is linked to obesity.<sup>5 6 7 8</sup> One longitudinal trial in young adult women found that the consumption of one additional fast food meal/week was associated with an increase in energy intake of 56 kcal/day and a weight gain of 0.72 kg over and above the average weight gain that naturally occurs over a 3-year period.<sup>9</sup> Furthermore, studies have shown that individuals consume more calories when presented with a large portion than when presented with a smaller food portion.<sup>10</sup> Many studies have found an acute effect of portion size on food intake, but a recent study has found that increased caloric intake is sustained over many days, strengthening the evidence that larger portions are associated with higher energy intake and increased body weight.<sup>11</sup>

5. Childhood obesity rates are alarmingly high. As children's body weight have increased, so has their consumption of fast foods and soft drinks.<sup>12</sup> Fast food consumption increases as children age, and with it, so do calories. In Project EAT (Eating Among Teens), a study that aimed to identify various factors associated with the nutritional intakes of adolescents, 75% of adolescents reported eating at a fast food restaurant during the previous week.<sup>13</sup> Male students in grades 9-12 were more likely than those in grades 7 and 8 to report visiting a fast food outlet  $\geq 3$  times in the previous week; and both male and female students who reported eating at a fast food restaurant  $\geq 3$  times in the past week had energy intakes 40% and 37% higher respectively, than did those who did not eat at a fast food outlet.

6. Fast food consumption is correlated with higher calorie intake among adults as well as children. In a 1994-1996 survey of 17,370 adults and children, adults who ate at fast food restaurants consumed 205 more calories per day than those who did not, and children ate 155 more calories.<sup>14</sup>

7. It is well known that overweight and obesity are associated with increased morbidity, which translates into increased risk of mortality.<sup>15</sup> It is also well known that decreasing calorie intake reduces and prevents weight gain. Furthermore, even small weight losses lead to significant improvements in health profiles.<sup>16</sup>

8. The mission of the New York Obesity Research Center is to help reduce the incidence of obesity and related diseases through leadership in basic research, clinical research, epidemiology and public health, patient care, and public education. Part of patient care and public education is to help people cope with an obesogenic environment. All of us who counsel obese patients have heard the familiar mantra of intervention: diet, physical activity, and behavior modification. Behavior modification is one successful strategy for managing obesity because it teaches patients specific skills to make it easier for them to modify their diet and improve their physical activity to lose and maintain a healthier weight. Although physical activity is important for prevention of weight gain and for health, most of the recent rise in obesity is attributable to excess caloric intake, which is why we counsel patients strongly on their calorie intake.<sup>17</sup> Yet McDonald's, for example, as described in DeMuth's declaration, stresses physical activity (calorie expenditure) over reducing calories (calorie intake). It has been shown that increasing physical activity, without a concomitant reduction in energy intake, does not lead to much weight loss.<sup>18</sup>

9. Similarly, in Haugen's declaration on Burger King, she states "while calories play an important role in weight management, most nutritionists agree that overemphasis on one or a few nutrients is unlikely to help consumers properly manage their diet or health." The rule of thermogenesis never waivers: healthy eating may be important, but for weight loss, only calories count. Haugen describes the disconnect between consumers' general interest in eating healthier and controlling their weight, on the one hand, and their state of knowledge about the daily recommended intake of such nutrients." Consumers are confused about the daily recommended intake, which is why giving consumers a

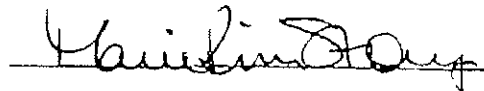


simple method for calorie comparison is so important. By mandating that all chain restaurants post calories, §81.50 will help consumers decide between a 400 calorie hamburger or an 800 calorie hamburger.

10. Self-monitoring or record-keeping is a fundamental element of behavior modification. Food records are a mainstay of any weight management program -- from Weight Watchers to medically supervised programs to the Diabetes Prevention Program.<sup>19</sup> Record keeping's most important role is raising patients' awareness of their food intake. The act of observing and recording one's behaviors can change behaviors, helping patients reach their goals.<sup>20 21</sup> One of the most difficult things for a patient is trying to accurately assess calories. Giving individuals information on the calorie content of foods, as §81.50 will do, will go hand-in-hand with current recommendations to control caloric intake. It is probable, that a person scanning a menu board for something to eat and drink, might substitute a 210 calorie medium sized drink for a diet soda worth zero calories.<sup>22</sup> These are the kind of substitutions that can help reduce obesity. §81.50 targets one component of the energy balance equation, giving people the information they need to make informed health decisions. Providing consumers with calorie information at the point of purchase will likely help many individuals control their body weight

I declare under penalty of perjury pursuant to 28 U.S.C. §1746 that the foregoing is true and correct.

Executed on February 7, 2008



Marie-Pierre St-Onge

<sup>1</sup> St-Onge MP, Keller KL & Heymsfield SB. Changes in childhood food consumption patterns: a cause for concern in light of increasing body weights. *Am J Clin Nutr* 2003; 78:1068-1073.

<sup>2</sup> French SA, Story M, Jeffery RW. Environmental influences on eating and physical activity. *Annu Rev Public Health* 2001; 22:35-57.

<sup>3</sup> Schluter G, Lee C. Changing food consumption patterns: their effects on the US food system, 1972-92. *Food Rev* 1999;22:309-335.

<sup>4</sup> Nielson S, Siega-Riz AM, Popkin B. Trends in energy intake in the U.S. between 1977 and 1996: similar shifts seen across age groups. *Obesity Research* 2002; 10(5): 370-378.

<sup>5</sup> Jeffery RW, Baxter J, McGuire M, Linde J. Are fast food restaurants an environmental risk factor for obesity? *Int'l J Behav Nutr and Phys Act* 2006;3:2.

<sup>6</sup> Bowman S, Vinyard B. Fast food consumption of US adults: impact on energy and nutrient intakes and overweight status. *Journal of the American College of Nutrition* 2004; 23(2):163-168.

<sup>7</sup> French SA, Harnack L, Jeffery RW. Fast food restaurant use among women in the Pound of Prevention study: dietary, behavioral and demographic correlates. *International Journal of Obesity* 2000; 24:1353-1359.

<sup>8</sup> Yamamoto JA, Yamamoto JB, Yamamoto BE, Yamamoto LG. Adolescent calorie-fat menu ordering at fast food restaurants compared to other restaurants. *Hawaii Med J* 2006 Aug;65(8):231-6.

<sup>9</sup> French SA, Harnack L, Jeffery RW. Fast food restaurant use among women in the Pound of Prevention study: dietary, behavioral and demographic correlates. *Int J Obes Relat Metab Disor* 2000; 24:1353-1359.

<sup>10</sup> Fisher JO, Arreola A, Birch LL, Rolls BJ. Portion size effects on daily energy intake in low-income Hispanic and African American children and their mothers. *AJCN* 2007;86:1709-16.

<sup>11</sup> Rolls BJ, Roe LS, Meengs JS. The effect of large portion size on energy intake is sustained for 11 days. *Obesity* 2007;15:1535-43.

<sup>12</sup> St-Onge MP, Keller KL & Heymsfield SB. Changes in childhood food consumption patterns: a cause for concern in light of increasing body weights. *Am J Clin Nutr* 2003; 78:1068-1073.

<sup>13</sup> French SA, Story M, Neumark-Sztainer D, Fulkerson JA, Hannan P. Fast food restaurant use among adolescents: associations with nutrient intake, food choices and behavioral and psychosocial variables. *Int J Obes Relat Metab Disord* 2001; 25:1823-1833.

<sup>14</sup> Paeratakul S, Perdinand D, Champagne C, Ryan D, Bray G. Fast-food consumption among US adults and children: dietary and nutrient intake profile. *Journal of American Dietetic Association* 2003; 103(10):1332-1338.

<sup>15</sup> St-Onge, MP & Heymsfield SB. Overweight and obesity are linked to lower life expectancy. *Nut Rev* 2003; 61(9):313-316.

<sup>16</sup> National Institutes of Health. Clinical guidelines on the identification, evaluation and treatment of overweight and obesity in adults – the evidence report. *Obes Res* 1998;6:S1S-209S.

<sup>17</sup> Kumanyika SK. Global Calorie Counting: A Fitting Exercise for Obese Societies. *Annu Rev Public Health*. 2008 Jan 3 [Epub ahead of print].

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<sup>20</sup> Baker RC, Kirschenbaum DS. Self-monitoring may be necessary for successful weight control *Behav Ther.* 1993;24:377-394

<sup>21</sup> Foreyt JP, Goodrick GK. Factors common to successful therapy of the obese patient. *Med Sci in Sports & Exer.* 1991;23:292-297

<sup>22</sup> St-Onge & Heymsfield SB. Usefulness of artificial sweeteners for weight control. *Nutr Rev* 2003; 61: 219-221

**POPKIN  
DECL.**

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CPC

PAGE 02/13

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

NEW YORK STATE RESTAURANT  
ASSOCIATION,

2008 Civ 1000

Plaintiff,

-against-

DECLARATION OF

NEW YORK CITY BOARD OF HEALTH,  
NEW YORK CITY DEPARTMENT OF HEALTH  
AND MENTAL HYGIENE, and Thomas R. Frieden,  
In His Official Capacity as Commissioner  
Of the New York City Department of Health  
And Mental Hygiene,

BARRY M. POPKIN

Defendants.

BARRY M. POPKIN hereby declares under penalty of perjury:

**Background and Qualifications:**

1. I am a Distinguished Professor of Global Nutrition in the Department of Nutrition  
in the Schools of Medicine and Public Health, Professor of Economics, and

Director of the Interdisciplinary Center for Obesity Research at the University of North Carolina at Chapel Hill. I have served on a number of national advisory committees related to diet and obesity and health including the Nutrition Component of the President's Select Panel on Child Health 2 decades ago. I have a very large program of NIH grants that focus on dietary behavior, the causes of selection of away-from-home food intake, and obesity and diabetes. My research in the U.S. focuses completely on dietary behavior and health among children and adults. I currently serve on a number of National Academy of Science and other international advisory panels. I have published more than 260 journal articles. My works on U.S. dietary behavior relevant to this specific topic of restaurant food consumption have been published in the Journal of the American Medical Association, the New England Journal of Medicine and Nature Reviews, among dozens of other major health, nutrition, and economics journals.

2. My research on this topic is quite wide-reaching and well-cited. Domestically, my research programs focus on understanding dietary behavior, specifically related to eating patterns, trends, and sociodemographic determinants of dietary patterns. This U.S. work also includes a series of NIH grants to study how socioeconomic change related to factors such as availability and pricing of fast food restaurants and sit-down restaurants affects diet and obesity in the 20-thousand person National Longitudinal Study of Adolescent Health my center is running and in a second 20-year long longitudinal study-CARDIA. I have researched and published extensively on the nutrition transition and the rapid changes in obesity that are occurring worldwide; dynamic changes in diet, physical activity and

inactivity; body composition changes (and the factors responsible for these changes); consequences of these changes; and program and policy options for managing change. Not only have I worked with the U.S. government but I also actively am involved in guiding the Ministry of Health in Mexico on related topics and am active with the national organizations dealing with a similar topic in China and Brazil.

3. Given my experience, training and expertise, I am highly qualified to offer informed opinions on issues related to obesity and its causes and consequences and provide my full support of the Declaration made by Kiyah J. Duffey regarding the proposed regulation 81.50 which was passed into law by the New York City Board of Health. I believe that the evidence and statements made by Ms. Duffey are accurate and reflect the current state of knowledge regarding these topics.
4. I have reviewed and worked with Ms. Kiyah Duffey on her declaration. I have suggested changes and completely approve the final document.

I wish to add several more points. At this time there is no meaningful research to show that providing caloric labeling will hurt individuals and there is significant scientific evidence that posting calories may help. The literature clearly shows that a sizable segment of our society does use food labeling and benefit from this. I have published numerous scientific, peer reviewed articles on the association of high energy-dense foods from fast food restaurants and increased weight. Clearly not every consumer will utilize or benefit from caloric labeling or any other educational or information disclosure effort.

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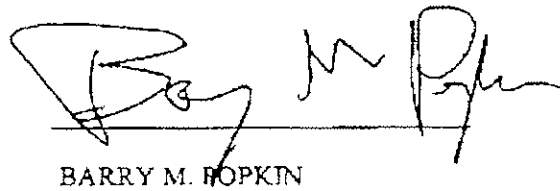
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However, the measure will benefit many persons and has little, if any, potential to do harm.

I declare under penalty of perjury pursuant to 28 U.S.C. §1746 that the foregoing is true and correct.

Executed on February 8, 2008



A handwritten signature in black ink, appearing to read 'Barry M. Hopkin', is written over a horizontal line.

BARRY M. HOPKIN



PI- SUNGER  
DECL.

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

NEW YORK STATE RESTAURANT  
ASSOCIATION,

Plaintiff,

2008 Civ 1000

-against-

NEW YORK CITY BOARD OF HEALTH,  
NEW YORK CITY DEPARTMENT OF HEALTH  
AND MENTAL HYGIENE, and Thomas R. Frieden,  
In His Official Capacity as Commissioner  
Of the New York City Department of Health  
And Mental Hygiene,

Defendants.

DECLARATION OF  
Xavier Pi-Sunyer

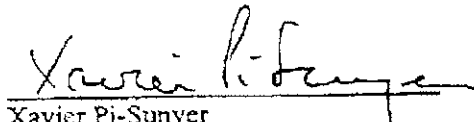
I, Xavier Pi-Sunyer, MD, MPH hereby declares under penalty of perjury:

1. I am Director of the Division of Endocrinology at St. Luke's-Roosevelt Hospital and Professor of Medicine at Columbia University. I am also of the NIH-supported New York Obesity Research Center, one of four such NIH centers in the USA. I have an MD from Columbia University and an MPH from Harvard University. I have published over 200 peer-reviewed publications in the area of obesity and diabetes. I led the National Heart, Lung, and Blood Institute's task force that developed the *Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults*. I have served on the FDA Science Board and on a number of Institute of Medicine task forces on nutrition. I have served as president of the American Diabetes Association, the American Society of Clinical Nutrition, and the North American Association for the Study of Obesity.
2. My colleague, Dr. Marie-Pierre St. Onge, has written a declaration in support of the New York Department of Health's proposal §81.50. I want to align myself with what she has written. I concur with her statements.
3. I believe that §81.50 could be helpful to consumers in allowing them to make more informed choices. The weight of the scientific evidence indicates that providing consumers with calorie information at the point of purchase will help them make lower-calorie selections. On a population-scale, given that 66% of adults nationwide are overweight or obese, the rule could help prevent weight gain for those who are at a healthy weight now, slow weight gain among people who are overweight and prone towards obesity and support

weight loss efforts for people who need them - all with beneficial health effects.

I declare under penalty of perjury pursuant to 28 U.S.C. §1746 that the foregoing is true and correct.

Executed on February 8th, 2008

  
Xavier Pi-Sunyer

**SCHWARTZ  
DECL.**

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK**

----- x  
**NEW YORK STATE RESTAURANT ASSOCIATION,**

**Plaintiff,**

**-against-**

**DECLARATION OF  
MARLENE B. SCHWARTZ,  
Ph.D.**

**NEW YORK CITY BOARD OF HEALTH, NEW  
YORK CITY DEPARTMENT OF HEALTH AND  
MENTAL HYGIENE, and THOMAS R. FRIEDEN, In  
His Official Capacity as Commissioner of the New York  
City Department of Health and Mental Hygiene,**

**08 Civ. 1000 (RJH)**

**Defendants.**  
----- x

MARLENE B. SCHWARTZ, Ph.D., hereby declares under penalty of perjury:

1. I am the Deputy Director for the Rudd Center for Food Policy and Obesity at Yale University in New Haven, CT and Senior Research Scientist in the Psychology Department at Yale University. I received a Ph.D. in Psychology from Yale University in 1996 and I am a licensed psychologist in the State of Connecticut. I have conducted research and published papers in peer reviewed journals on many aspects of the etiology, prevention, and treatment of obesity. I have substantial clinical experience treating obesity and eating disorders, as I co-directed the Yale Center for Eating and Weight Disorders for a decade. I have no conflicts of interest to declare. My training and research have been funded exclusively by grants from the American Psychological Association, the Robert Wood Johnson Foundation, the National Institute of Mental Health, the Rudd Foundation, and Yale University. My CV is attached.

2. The New York City Board of Health enacted §81.50 in response to the obesity epidemic in New York City. The purpose of §81.50 is to inform consumers of

chain restaurants of the calorie content of food options at the time and location at which consumers make their food purchase decisions. My clinical experience working with obese individuals who wish to lose weight and my knowledge of the relevant research leads me to conclude the following: (a) there is very clear and consistent research that consumers are not accurate in determining the calorie content of menu options at these restaurants (e.g., Chandon & Wansink, 2007), (b) without this information, it is virtually impossible to accurately track one's daily caloric intake when eating out, (c) calorie information **at the point of purchase** has a strong likelihood of educating consumers of the caloric content of the foods they are eating when they eat out, and (d) menu labeling will provide individuals with the opportunity to make nutritious choices. I also believe this measure has a reasonable likelihood of encouraging the restaurant industry to create and provide healthier options on their menus.

3. In his Declaration for the New York State Restaurant Association, Dr. Allison makes a number of assertions I would like to address.

4. Early in his declaration (p. 4), Dr. Allison states that he is restricting his comments to “whether there is scientific evidence showing that the revised Regulation 81.50...will achieve the objective of reducing obesity levels among NYC residents and/or people that dine in NYC. “ He states that he will not render an opinion regarding whether §81.50 is “‘good’, legally defensible, fair, adverse to legitimate economic interests, or ‘should’ be adopted...” However, the question for consideration is not whether there is incontrovertible scientific proof that §81.50 will reduce obesity levels in NYC residents, but rather whether the Department has legitimate reason to believe that it might contribute to reducing obesity levels or slowing the obesity epidemic in NYC. These

standards are quite different. Thus Dr. Allison has excused himself from addressing the scientific question that must be answered, and instead has introduced a scientific standard that is entirely inappropriate for policy-making, and in so doing is diverting attention from the key issues. The use of scientific evidence for policy-making is discussed in the declaration of Commissioner Frieden in the section: Standard of Evidence for Public Policy.

5. In providing a rationale for §81.50 in its Notice of Intent, the Department claimed that:

- Obesity is epidemic and an increasing cause of disease
- The obesity epidemic is mainly due to an excess of calorie consumption
- Chain restaurants serve food that is associated with excess calorie consumption and weight gain
- Consumers do not know how many calories are in restaurant foods and frequently underestimate the caloric content of foods
- Point-of-decision calorie information helps consumers
- Voluntary activities by restaurants to supply calorie information fall woefully short

Dr. Allison reframes these into seven "Propositions" and discusses each. In his discussion (pages 9-11) he fully accepts the first six of his "propositions", which correspond to the first four claims above. He further considers a "proposition" that "restaurants and restaurant foods are contributing to the epidemic in some manner that is above and beyond the contribution offered by any source of food energy" (p. 10). The Department did not word any claim in this way, and in fact I know of no expert who

makes such a claim. In fact, Dr. Allison's wording represents a broader framing of the risks of restaurant food: "I believe it is reasonable to conjecture that providing calorie information at the point of purchase in restaurants (especially in fast food restaurants) might be beneficial in reducing obesity levels". **Thus the plaintiff's expert is agreeing with the Department's rationale for §81.50.**

6. Dr. Allison does not address the Department's claims 5 and 6 above, but these are central to the rationale for §81.50. As stated in Dr. Frieden's Declaration, when consumers are provided calorie information, through such means as labeling of packaged food, large percentages of them report using this information and changing their purchases based on this information (Burton et al., 2006; IFIC 2007; Levy & Derby, 1996).

7. In his Declaration, Dr. Allison fundamentally agrees with the claims made by the Department as its rationale for §81.50. To the extent that Dr. Allison disagrees with the Department it is disagreement on claims that the agency has not made and does not need to make to justify the rule. Thus Dr. Allison's declaration supports §81.50.

8. When reviewing the research literature and drawing conclusions about the strength of the evidence, Dr. Allison confuses two distinct models used to approach the problem of obesity: the "medical model" and the "public health model" (see Schwartz & Brownell, 2007). Dr. Allison clearly articulates the medical model, which takes the view that health professionals use treatments that are developed for individuals and can be reasonably tested in randomized controlled trials (RCTs). This model is appropriate for testing new drug therapies or other medical treatments, but is not the typical standard for public policy changes. For instance, if lead in gasoline creates pollution and harms health,



one does not wait for a randomized trial showing that taking lead from gasoline makes people healthier. No randomized trials were done to show that placing nutrition labeling on packaged food drives down disease rate. Dr. Allison acknowledges this point himself in his declaration when he states that "for practical or ethical reasons, it is often impossible to conduct an RCT to address a particular question."

9. Dr. Allison justifies his decision to use the National Heart, Lung, and Blood Institute's rating scale for research on clinical guidelines for the treatment of obesity by citing his own recent paper from a project supported by the Coca-Cola Company entitled "Toward the reduction of population obesity: Macrolevel environmental approaches to the problems of food, eating and obesity" (Faith et al, 2007). This paper reviews a range of public health approaches to obesity (e.g., taxing foods, manipulating access to certain foods) and finds that "more studies are need to justify that altering these macro-environmental variables will necessarily reduce population obesity" (p. 205). But again, the authors acknowledge that while an RCT is the gold standard, "For the majority of possible approaches considered in this report, it would be extraordinarily difficult if not impossible to conduct such a study. It is difficult to blind people to many of the things under study, randomization is often impractical, and running studies for a sufficiently long period of time on a sufficiently large number of subjects may also be impractical" (p 223). This suggests again that Dr. Allison understands that an RCT is **not** the appropriate research method for large public health interventions.

10. The appropriate way to approach the research relevant to menu labeling is to examine it through the public health model. This model focuses on **the public's right**

**to safety and health.** Using the Allison logic, the Department wanting to sanction restaurants with cockroaches would first be required to conduct an RCT showing that patrons get healthier when the cockroaches are gone.

11. It is most important to consider whether there is reasonable evidence of benefit from a policy and a small chance of harm. In section H, Dr Allison reviews studies to support his conjecture that providing nutritional information for food sold in restaurants “could even be harmful” and states that such conjecture is “reasonable.” This is a stunning claim. I review the same studies below and conclude **that it is not reasonable to conjecture that menu labeling is likely to create any harm.**

12. Dr. Allison begins his argument by stating that the intuitions of even “well-trained experts are **often** [emphasis added] wrong especially on issues involved human behavior.” To support his conjecture, he selectively chooses four “examples,” which when read carefully and viewed in the context of the larger fields they represent (e.g., Stice, Shaw & Marti, 2007), as well as the “history of science, medicine, and psychology” **do not** provide evidence that expert intuition is **often** wrong, or leads to unintended harm.

13. To further support his position that conjecture about unintended harm is “reasonable,” Dr. Allison reviews four additional studies in greater detail. Again, when examined carefully, none provides convincing support for his concern. He first quotes the dramatic and misleading press release title (not the actual report) from a CDC-sponsored study on increasing student access to fresh fruits and vegetables (CDC, 2006). This study actually found that the variety of fruits and vegetables ever eaten **significantly increased** for all three grades examined (5<sup>th</sup>, 8<sup>th</sup>, and 10<sup>th</sup> grade), and the attitude decrease

cited by Dr. Allison was only observed in the 5<sup>th</sup> graders; the 8<sup>th</sup> graders had significantly **positive** increases in attitudes about fruit, their belief they can eat more fruit and their willingness to try it and 10<sup>th</sup> graders did not exhibit a significant change. It is notable that this study lacked a control group, which if present, would have been able to inform the researchers whether the decrease in positive attitudes in 5<sup>th</sup> graders is part of a natural developmental trend. In other words, it is possible that most children develop negative attitudes about fruits and vegetables between ages 9 and 10 due to other factors, such as exposure to food marketing for unhealthy foods at an age when they are still too young to understand the intent of advertising.


14. Dr. Allison cites a study by Boon et al (2002) as another example of possible negative outcomes from menu labeling. In reading this study carefully, it is clear that the intervention tested was not to tell people the number of calories in a range of food choices and allow them to choose what to eat, but rather, to tell people that the food they were being served (and were expected to eat as part of the taste-test experiment) was either high or low in calories – without disclosing the actual number of calories. The strongest finding from this study was that people eat more when distracted, suggesting that people should try to focus on enjoying their meal while eating, rather than doing other things. But, for the conditions of this study to be replicated in NYC restaurants, it would involve having the waitresses (instead of the researchers in this study) go around and tell patrons, “that ice cream is extra creamy” or “that ice cream is from a firm that specializes in light products....” (p. 5), **not** having restaurants post calorie information on menus to be used at the point of purchase. This study is therefore irrelevant to the question of unintended harm from menu labeling.

15. Dr. Allison cites the Aaron et al.(1995) twice. First, in Table 1, he says it is “not directly relevant because the independent variable is calorie and fat content, not just calorie content” but then on page 32 he cites it as evidence of a possible negative effect menu labeling because calorie labeling in a college cafeteria led to an increase in calorie consumption for students. When the results from this short intervention are examined carefully it appears that the finding is being driven primarily by unrestrained eaters and males in the sample. This finding can be understood in the context of the self-reported data in the Krukowski et al (2006) study, which also found that college males say they are not likely to use restaurant food caloric information. These studies suggest that college males are a unique group that may be less likely to pay attention to and use menu labels to improve their diet. This is interesting given that even sedentary 19-20 year old males require an average of 2600 calories (according to mypyramid.gov), which is the highest number of calories in the sedentary column (active males this age require 3000 calories). This is quite different than the 2000 calorie reference that is given on the nutrition facts label, and perhaps makes this subgroup of the population feel that nutrition labels were not designed for them. Future initiatives may be useful to target this subgroup and help them find ways to use calorie information to improve their diets, but my view is that the available data do not cross the threshold of evidence strong enough to cause concern regarding unintended negative consequences of menu labeling.

16. Dr. Allison states that there is not “evidence that the method of providing caloric information mandated by §81.50 will reduce levels of obesity more than the methods currently used by the affected restaurants to provide this information” (p. 30). He neglects to note, however, that there is evidence that the industry’s recent efforts to create an image of healthfulness by making health claims on their foods **without providing accurate, factual calorie information** has made consumer’s ability to accurately estimate calories **worse** by creating a “health halo” effect (Chandon & Wansink, 2007). In other words, if the industry is not mandated to provide nutrition facts, rather than non-regulated self evaluations of the healthfulness of their foods, one can reasonably conjecture that **consumers are likely to underestimate calories by an even greater margin.**

17. In summary, Dr. Allison agrees with the claims that the Department has made in providing its rationale for §81.50 and agrees that §81.50 may reduce obesity levels in New York City, and thereby supports the regulation. To the extent that Dr. Allison criticizes the reasoning in the Notice of Intent for §81.50, his criticisms reflect an incorrect application of scientific evidence to policy-making. I declare under penalty of perjury pursuant to 28 U.S.C. §1746 that the foregoing is true and correct.

Executed on February 8, 2008.

  
MARLENE B. SCHWARTZ, PhD

## References

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- Boon B, Stroebe W, Schut H, Ijntema R. Ironi processes in the eating behavior of restrained eaters. *Br J Health Psycholo*. 2002 Feb;7(Pt 1): 1-10.
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